

Serial No. 10/694,467

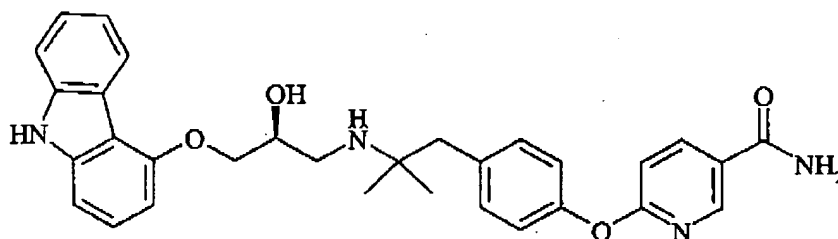
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Remarks§101 Double Patenting

Claims 53, 55, 57, 61 and 63 stand rejected under 35 U.S.C. §101 over claims 8, 16, 30, 38 and 39 of the '352 patent. Of those rejected claims, only claims 53 and 55 are still pending. Applicants respectfully traverse the rejection in view of the amendments provided herewith and request withdrawal of same.

Claims 53 and 55 of the present application are directed to a compound of the formula:



and a formulation

containing said compound, respectively.

Claim 8 of the '352 patent is directed to the compound pictured above "or a pharmaceutically acceptable salt or solvate" thereof. Claim 16 of the '352 patent is directed to a formulation containing "a compound of claim 8" (Emphasis added to show that the subject matter of claim 16 is not limited to a formulation containing only the pictured compound but also includes formulations containing a salt or solvate of the pictured compound). The remaining claims from the '352 patent recited by the Examiner are directed to various methods of treatment and are believed to be no longer relevant in view of the amendments provided herewith.

Applicants note that a rejection under 35 U.S.C. §101 is proper only when the claims at issue are drawn to identical subject matter previously patented. Applicants respectfully assert note that according to the Manual of Patent Examination Procedure (MPEP) §804(T)(A),

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A reliable test for double patenting under **35 U.S.C. 101** is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

Applicants assert that since the subject matter of claims 8 and 16 from the '352 patent include salts and solvates therein whereas present claims 53 and 55 do not that the test enunciated above for double patenting is failed. In other words, claims 8 and 16 from the '352 patent read on a pharmaceutical salt of the compound pictured above whereas claims 53 and 55 do not. Thus, Applicants respectfully assert that the present rejection is improper and request withdrawal of same.

JCDOTDP: The '352 Patent

Claims 53-64 stand rejected under the JCDOTDP over claims 1-16 and 22-39 of the '352 patent. A terminal disclaimer may be used by Applicants to overcome this rejection.

While not necessarily agreeing with the Examiner's assessment of the claims, in order to expedite prosecution, Applicants provide a terminal disclaimer complying with 37 C.F.R. §§ 1.130(b), 1.321(c), and 3.73(b) over U.S. Patent No. 6,303,634. Pursuant to *Quad Environmental Technologies v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), the filing of this Terminal Disclaimer is not an admission or acquiescence by Applicants to, nor shall act as an estoppel upon the Applicants, on the merits of the rejection. Applicants maintain that said Terminal Disclaimer obviates this rejection of the pending claims.

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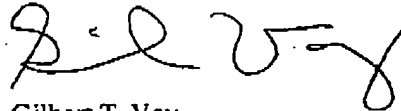
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Indefiniteness

Claims 57, 58, 61 and 62 stand rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph. Of those claims, only claims 58 and 62 are still pending. The Examiner contends that since claims 58 and 62 do not recite "an effective amount" of an active ingredient, said claims may be rendered "inoperable".

Without agreeing or disagreeing with any of the analysis provided by the Examiner, Applicant has accepted the Examiner's invitation to alter the present claims (by amending claims 58 and 62 to recite "a pharmaceutically effective amount." Applicants respectfully assert that the present claims are definite and this rejection is not applicable to any of the now pending claims.

Respectfully submitted,



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JUN 15 2005